ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2020-0084; FRL-7810-02-OAR]

RIN 2060-AU80

Protection of Stratospheric Ozone: Extension of the Laboratory and Analytical Use Exemption for Essential Class I Ozone-Depleting Substances

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is taking final action to revise regulations governing the production and import of class I ozone-depleting substances in the United States to indefinitely extend the global essential laboratory and analytical use exemption. This exemption currently expires on December 31, 2021, and this final action allows for continued production and import of class I substances in the United States solely for laboratory and analytical uses that have not been identified by the Environmental Protection Agency as nonessential. This final action is taken under the Clean Air Act, and is consistent with a decision by the Parties to the *Montreal Protocol on Substances that Deplete the Ozone Layer* to extend the global laboratory and analytical use exemption indefinitely beyond 2021. The proposed rule associated with this final action was published on August 7, 2020, and we received no adverse comments.

DATES: This final rule is effective on **[INSERT DATE 30 DAYS AFTER PUBLICATION IN FEDERAL REGISTER].**

ADDRESSES: The Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA-HQ-OAR-2020-0084. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information may not be publicly available, e.g., Confidential Business Information or other

information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. All other publicly available docket materials are available electronically in https://www.regulations.gov. Due to public health concerns related to COVID-19, the EPA Docket Center and Reading Room are closed to the public with limited exceptions. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Andy Chang, U.S. Environmental Protection Agency, Stratospheric Protection Division, telephone number: 202-564-6658; or email address: chang.andy@epa.gov. You may also visit our website at https://www.epa.gov/ods-phaseout/phaseout-exemptions-laboratory-and-analytical-uses for further information.

SUPPLEMENTARY INFORMATION: Throughout this document, whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is the Background for this Action?

A. What is the Agency's Authority for this Final Action?

The Clean Air Act (CAA) provides EPA the authority to implement the *Montreal*

Protocol on Substances that Deplete the Ozone Layer's (Montreal Protocol's) phaseout schedules for ozone-depleting substances (ODS) in the United States. Relevant to this rulemaking, CAA section 604 requires EPA to issue regulations phasing out production and consumption of class I[1] ODS according to a prescribed schedule; our phaseout regulations for class I ODS are codified at 40 CFR part 82, subpart A.

B. Summary of EPA's Proposed Rulemaking and Public Comments

EPA's August 7, 2020, proposed rulemaking (see 85 FR 47940) sought to align a provision in EPA's regulations governing the production and import of class I ODS regarding the essential laboratory and analytical use exemption (referred to hereafter as the "L&A exemption") with a recent decision taken by the Parties to the Montreal Protocol to extend the global L&A exemption indefinitely.[2] In the United States, laboratory distributors currently supply around 1,000 laboratories, and consumption[3] for laboratory use was approximately 4.4 ODP-weighted metric tons in 2018 under the L&A exemption[4] and 4.2 ODP-weighted metric tons in 2019 under the L&A exemption.[5] The global L&A exemption is implemented domestically through EPA's regulations at 40 CFR part 82, subpart A and the current exemption is in effect in the United States through December 31, 2021. In the proposed rulemaking (85 FR 47940), EPA proposed to remove the December 31, 2021, time restriction, allowing for continued production and import of class I ODS in the United States after that date for laboratory and analytical uses that have not been

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[1] Under the CAA, certain ODS are classified as "class I" substances. Class I substances are listed in Appendix A to 40 CFR part 82, subpart A.

[2] *Decision XXXI/5: Laboratory and Analytical Uses*, available online at: https://ozone.unep.org/treaties/montreal-protocol/meetings/thirty-first-meeting-parties/decisions/decision-xxxi5

[3] Consumption is defined in § 82.3 as "production plus imports minus exports of a controlled substance (other than transhipments, or used controlled substances)."

[4] These 2018 data are available in the docket to this rule as well as on the Montreal Protocol's Ozone Secretariat's Data Centre webpage: https://ozone.unep.org/countries/data-table.

[5] At the time of publication for the proposed rulemaking, the 2019 data were not yet available, but can now be found on the Montreal Protocol's Ozone Secretariat's Data Centre webpage: https://ozone.unep.org/countries/data-table. Data specific to the United States' amounts consumed for laboratory and analytical uses, including 2019 data, can be found on this webpage: https://ozone.unep.org/countries/profile/usa. These data have been added to the docket for this rulemaking.

identified by EPA as nonessential.

During the public comment period for the proposed rulemaking, which ended on October 6, 2020, EPA received a total of two comments which are publicly available in the docket. Both comments were in support of our proposed action; one comment noted that the proposed action was a cost- and time-effective revision, and the other comment supported the notion that laboratories could continue to obtain necessary and essential materials while being mindful of potential environmental impacts. EPA acknowledges the comments and concludes that they support the final action and do not require further response.

C. Potentially Impacted Entities

This final rule may potentially impact individuals or groups that manufacture, process, import, or distribute into commerce certain ODS and mixtures. These impacted entities and their associated North American Industrial Classification System (NAICS) codes may include but are not limited to:

- Basic chemical manufacturing (NAICS code 3251);
- Pharmaceutical preparations manufacturing businesses (NAICS code 325412);
- Other chemical and allied production merchant wholesalers (NAICS code 424690);
- Environmental consulting services (NAICS code 541620);
- Research and development in the physical, engineering, and life sciences (NAICS code 54171); and
- Medical laboratories (NAICS code 621511).

This list is not intended to be exhaustive; rather, it provides a guide for readers regarding entities likely to be affected by this final action. The NAICS codes provided above may assist in determining whether this final rule might apply to certain entities. Other types of entities not listed could also be affected, and EPA recommends that you consult the person listed under "**FOR FURTHER INFORMATION CONTACT"** if there are applicability

questions.

D. Background of the Laboratory and Analytical Use Exemption

The United States was one of the original signatories to the 1987 Montreal Protocol and ratified it on April 12, 1988. After ratification, Congress enacted, and President George H.W. Bush signed into law, the CAA Amendments of 1990, which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, to ensure, among other things, that the United States could satisfy its obligations under the Montreal Protocol.

The Montreal Protocol is a multinational environmental agreement to protect Earth's ozone layer by phasing out the consumption and production of most chemicals that deplete it. The Montreal Protocol provides a set of schedules to phase out ODS and also provides for mechanisms to establish certain specific and limited exemptions. For most class I ODS, the Parties to the Montreal Protocol may agree to grant exemptions to the ban on production and consumption of ODS for uses that they determine to be "essential." For example, with respect to chlorofluorocarbons (CFCs), Article 2A(4) of the Montreal Protocol provides that the phaseout will apply "save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential." Similar language appears in the control provisions for other ODS, such as halons (Article 2B), carbon tetrachloride (Article 2D), and methyl chloroform (Article 2E). As defined by Decision IV/25 of the Parties, "use of a controlled substance should qualify as 'essential' only if: (1) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health." Decision VI/9 of the Parties established a time-limited exemption under the Montreal Protocol for essential laboratory and analytical uses, consistent with the specifications in Annex II of the report of the Sixth

Meeting of the Parties (MOP), which describes conditions applied to the exemption for laboratory and analytical uses such as purity, quantity, and specification for cylinders and handling for these controlled substances.

Consistent with the flexibility allowed for by the Parties, in 2001, EPA codified a L&A exemption in its domestic regulations (see 66 FR 14760, March 13, 2001). In the preamble to that rule, EPA determined that the statutory language in section 604 of the CAA provided grounds for the creation of a *de minimis* exemption for essential laboratory and analytical uses of certain class I ODS (id. at 14764-65). The 2001 rule explains how the controls in place for laboratory and analytical uses provide adequate assurance that very little, if any, environmental damage will result from the handling and disposal of the small amounts of class I ODS used in such applications due to the Appendix G requirements under 40 CFR part 82, subpart A, for small quantity and high purity. For example, class I ODS must be sold in cylinders three liters or smaller or in glass ampoules 10 milliliters or smaller, as per Appendix G. Since issuing the original exemption, EPA has not received information that would suggest that the current controls in place for laboratory and analytical use do not provide adequate assurance that very little, if any, environmental damage will result from the handling and disposal of class I ODS used in such applications. As discussed later in this notice, the quantities of class I ODS used for this exemption have declined substantially since the exemption was initially created.

As summarized in the proposal for this final action, the Parties subsequently issued several decisions related to the global exemption, including periodic extensions, and EPA has also revised the exemption in its domestic regulations several times (see 85 FR 47941–92, August 7, 2020). Under Decision XXVI/5 at the 26th MOP, the Parties extended the global L&A exemption until December 31, 2021, which EPA implemented domestically through a rulemaking in 2015 (see 80 FR 3885, January 26, 2015). More recently, in November 2019, at the 31st MOP, the Parties agreed in Decision XXXI/5 to "extend the

global laboratory and analytical-use exemption indefinitely beyond 2021, without prejudice to the parties deciding to review the exemption at a future meeting." The Decision also encourages parties to further reduce their production and consumption of ODS for laboratory and analytical uses and to facilitate the introduction of laboratory standards that do not require such substances.

II. What Action is EPA Taking?

EPA is finalizing its August 7, 2020, proposal to indefinitely extend the global L&A exemption for class I ODS in 40 CFR 82.8(b). This action makes the regulatory exemption indefinite unless or until it is limited or eliminated through future rulemaking, i.e., EPA still has the authority to review the scope of and need for the exemption at a future date. Upon the effective date of this final action, the regulations will no longer contain an expiration date for the exemption. The list of laboratory and analytical uses codified in Appendix G to 40 CFR part 82, subpart A, may also be revised through new rulemakings as alternatives are identified through new standards.

Consistent with the proposal, this final action also contains clarifying text to explain that the global L&A exemption allows for the production and import of class I ODS that have been phased out in the United States, subject to certain restrictions as described in Appendix G to 40 CFR part 82, subpart A, and subject to the recordkeeping and reporting requirements at 40 CFR 82.13(u) through (x). The previous text in 40 CFR 82.8(b) established the exemption for essential laboratory and analytical uses but did not explicitly state that the exemption is from the prohibitions on production and import of class I ODS, although that is clear from context and the explanation in a previous rule (see 66 FR 14760, March 13, 2001). Consistent with the proposal, this final rule states the exemption more explicitly.

As noted in the proposed rule, there are several reasons why the Agency is making these changes. This action is consistent with Decision XXXI/5 by the Parties to the

Montreal Protocol, and it will provide certainty with regards to the exemption without the need for periodic rulemakings to extend the exemption. This is important since non-ODS replacements for class I ODS may not be identified for all uses given the effort required to establish new analytical procedures for such small quantities of material. While some analytical procedures have transitioned, many ASTM International (formerly known as the American Society for Testing and Materials) and ISO (International Organization for Standardization) standards still require small amounts of ODS, and it could take years for standards organizations to develop alternatives and for laboratories to adopt the new standards.

From an environmental impact perspective, removing the deadline from the L&A exemption will also have little effect on the stratospheric ozone layer due to a combination of factors including the general decline of production and consumption of ODS for laboratory and analytical uses in the United States and the existing controls in place for laboratory and analytical uses.

Exempted consumption for laboratory and analytical uses in the United States peaked in 2004 at 55 ODP-weighted metric tons, and was only 4.4 ODP-weighted metric tons in 2018, which is a negligible amount.[6] Data for 2019, which became available after the publication date for EPA's proposed rulemaking, indicates that the exempted consumption for laboratory and analytical uses in the United States has decreased further to 4.2 ODP-weighted metric tons.[7] This sharp decline since 2004 indicates that many users (primarily laboratories) have been able to transition from ODS even with this exemption being available to them; as these laboratories continue to use non-ODS and/or continue to transition to non-ODS alternatives for laboratory and analytical uses, EPA anticipates that

[6] These data are available in the docket to this rule as well as on the Ozone Secretariat's Data Centre webpage: https://ozone.unep.org/countries/data-table.

[7] These data can now be found on the Montreal Protocol's Ozone Secretariat's Data Centre webpage: https://ozone.unep.org/countries/data-table. Data specific to the United States' amounts consumed for laboratory and analytical uses, including 2019 data, can be found on this webpage: https://ozone.unep.org/countries/profile/usa. These data have been added to the docket for this rulemaking.

the decreasing trend for class I ODS for exempted consumption will generally continue. However, certain laboratory and analytical procedures continue to require the use of class I ODS in the United States. In the United States, there are currently ten laboratory distributors that supply around 1,000 laboratories with primarily carbon tetrachloride but also small quantities of chlorobromomethane, CFCs, methyl chloroform, and methyl bromide. Maintaining this exemption would provide laboratories with essential class I ODS for which no alternatives are currently available, with negligible environmental impacts.

Additionally, this action does not make any change in the controls that are in place for laboratory and analytical uses, and as discussed above in the section titled, "*Background of the Laboratory and Analytical Use Exemption,"* EPA's March 13, 2001, rule explains how these controls provide adequate assurance that very little, if any, environmental damage will result from the handling and disposal of small amounts of class I ODS used in such applications. Further, EPA has the authority to review the scope of and need for the exemption at a future date, for example if alternative methods become available or consumption begins to increase. Lastly, as noted earlier in this notice, we received two supportive comments and no adverse comments on the proposed rule associated with this final action. Based on consideration of all this information and the two comments that both supported the proposed rule, EPA is finalizing the action as proposed.

EPA encourages laboratories to continue ongoing efforts to transition to methods that do not require the use of ODS, and to share such information when available, as it could assist others in similar situations.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2060-0170. The laboratory and analytical use exemption currently expires on December 31, 2021, and this action allows for continued production and import of class I substances in the United States solely for laboratory and analytical uses that have not been identified by EPA as nonessential, and therefore there are no PRA implications. This action indefinitely removes the expiration date for the existing exemption from the prohibitions in production and import of class I ODS.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action does not modify the recordkeeping and reporting requirements that apply to laboratory distributors who utilize the exemption. These requirements will continue to apply to distributors who use the exemption; however, the requirements are minimal and impose no significant burden. Further, nothing in this rule compels any entity to use the exemption. The Agency thus assumes that the burden reduction provided by the exemption from the phaseout on production and import of class I ODS outweighs the limited cost associated with recordkeeping and reporting. Otherwise, laboratory distributors could choose not to use the exemption, removing the need for relevant recordkeeping and reporting.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The

action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action. EPA periodically updates tribal officials on air regulations through the monthly meetings of the National Tribal Air Association and will share information on this rulemaking through this and other fora.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. Depletion of stratospheric ozone results in greater transmission of the sun's ultraviolet (UV) radiation to the earth's surface. The following studies describe the effects of excessive exposure to UV radiation on children: (1) Westerdahl J, Olsson H, Ingvar C. "At what age do sunburn episodes play a crucial role for the development of malignant melanoma," *Eur J Cancer* 1994; 30A:1647–54; (2) Elwood JM, Japson J. "Melanoma and

sun exposure: an overview of published studies," *Int J Cancer* 1997; 73:198–203; (3) Armstrong BK. "Melanoma: childhood or lifelong sun exposure," In: Grobb JJ, Stern RS, Mackie RM, Weinstock WA, eds. *Epidemiology, causes and prevention of skin diseases* (pp 63–66), London: Blackwell Science, 1997; (4) Whiteman D, Green A. "Melanoma and Sunburn," *Cancer Causes Control*, 1994; 5:564–72; (5) Heenan, PJ. "Does intermittent sun exposure cause basal cell carcinoma? A case control study in Western Australia," *Int J Cancer* 1995; 60:489–94; (6) Gallagher RP, Hill GB, Bajdik CD, et al. "Sunlight exposure, pigmentary factors, and risk of nonmelanocytic skin cancer I, Basal cell carcinoma," *Arch Dermatol* 1995; 131:157–63; (7) Armstrong, BK. "How sun exposure causes skin cancer: an epidemiological perspective," In: Hill D, Elwood JM, English DR (eds.) *Prevention of Skin Cancer. Cancer Prevention – Cancer Causes, vol. 3* (pp 89–116). Dordrecht: Springer, 2004. However, as described in the section above titled "What Action is EPA Taking?", the environmental impacts are expected to be negligible.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The environmental impacts of this regulation are expected to be negligible given the low level of ODS produced and imported for the L&A exemption. As such, there are no disproportionately high and adverse human health or environmental effects from this action on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

K. Congressional Review Act

This action is subject to the Congressional Review Act, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Imports, Methyl chloroform, Ozone, Reporting and recordkeeping requirements.

Michael S. Regan,
Administrator.

For the reasons set out in the preamble, 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671-7671q.

2. Section 82.8 is amended by revising paragraph (b) to read as follows:

§ 82.8 Grant of essential use allowances and critical use allowances.

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(b) There is a global exemption for the production and import of class I controlled substances for essential laboratory and analytical uses, subject to the restrictions in appendix G of this subpart, and subject to the recordkeeping and reporting requirements at § 82.13(u) through (x). There is no amount specified for this exemption.

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